K 002397

AUG 1 7 2000

2 Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 as implemented in 21 C.F.R. §807.92.

The submitter of this premarket notification is:

Paul Smolenski
Regulatory Engineer
Agilent Technologies
3000 Minuteman Road, MS 0135
Andover, MA 01810
Tel: (978) 659-3380
Fax: (978) 975-7324

This summary was prepared on June 30th, 2000.

The proprietary name of the device is the M2430 Diagnostic Ultrasound System with the 21420 transducer. These devices are commonly known as a diagnostic ultrasound system and transducer.

These devices are classified as follows:

90IYN	Ultrasonic Pulsed Doppler Imaging System
90IYO	Ultrasonic Pulsed Echo Imaging System
90ITX	Diagnostic Ultrasound Transducer

As stated in 21 CFR, parts 892.1550, 892.1560 and 892.1570, each of these generic types of devices have been classified as Class II.

The M2430 is a diagnostic ultrasound device. It consists of a system console containing the power supply and electronic circuitry required to generate the image, a display screen, and a connection to the separate transducer. It is substantially equivalent to the generic class of ultrasound systems including the Agilent Technologies M2410 (K954028) system.

The 21420 transducer is substantially equivalent to the generic class of ultrasound transducers including the Agilent Technologies 21330 (K954028).

The M2430 system and 21420 transducer function in a manner identical to all ultrasound systems and transducers. The system circuitry generates an electronic voltage pulse which is transmitted to the transducer. In the transducer, a piezo electric array converts the electronic pulse into a ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The differing acoustic properties of the

tissues in the body reflect some of the transmitted energy back to the transducer, where it is converted back to electrical signals and sent back to the system. In the system, advanced signal processing technologies convert the returned signals into images of the tissues. The Doppler functions of this system process the Doppler shift frequencies from the echoes of moving targets (such as blood), to detect and graphically display the Doppler shifts of these tissues as flow.

The M2430 is intended for diagnostic ultrasound imaging and fluid flow analysis.

The M2430 is substantially equivalent in safety and effectiveness to the predicates identified above:

- Both the predicate device and the M2430 are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- Both the predicate device and the M2430 have the same gray-scale and Doppler capabilities.
- Both the predicate device and the M2430 use essentially the same technologies for imaging, Doppler functions and signal processing.
- Both the predicate device and the M2430 have acoustic output levels below the applicable FDA limits.
- Both the predicate device and the M2430 are manufactured under equivalent quality systems.
- Both the predicate device and the M2430 are manufactured of materials with equivalent biosafety. The materials have been evaluated and found to be safe for this application.
- Both the predicate device and M2430 are designed and manufactured to the same electrical and physical safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2000

Agilent Technologies, Co.
c/o Carole Stamp
TUV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K002397
M2430 Diagnostic Ultrasound System
Regulatory Class: II
21CFR 892.1550/Procode: 90 IYN
21CFR 892.1560/Procode: 90 IYO
Dated: August 4, 2000
Received: August 7, 2000

Dear Ms. Stamp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the M2430 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

21420 Phased Array

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Agilent Technologies M2430 Diagnostic Ultrasound System
Transducer: 21420 Phased array transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N				N		N
	Abdominal	N				N		N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N				N		N
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N				N		N
	Cardiac Pediatric	N				N		N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Other Modes include Amplitude Doppler.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David G. Segerson

(Division Sign-Off)
Division of Reproductive, **Abdominal, ENT,** and Radiological Devices
510(k) Number K002397

K002397

1.2 Indications for Use Summary

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: **Agilent Technologies M2430 Diagnostic Ultrasound System**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N				N		N
	Abdominal	N				N		N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N				N		N
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N				N		N
	Cardiac Pediatric	N				N		N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Other Modes include Amplitude Doppler.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002397

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